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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,456	09/18/2001	Paul Young	689290-76	8167

7590 07/11/2003

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	16

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,456	YOUNG, PAUL	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-52* is/are pending in the application.

4a) Of the above claim(s) *18-35 and 37-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,51 and 52* is/are rejected.

7)☒ Claim(s) *2, 4-8, 10, and 51* is/are objected to.

8)☒ Claim(s) *1-35 and 37-52* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *9* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Sequence Match Listing (37 pages).

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-17); sequence elections of SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032; the amendment of claims 1-3, 5, 9, 11-15, 18, and 39; the cancellation of claim 36; and the addition of new claims 47-52 in Paper Nos. 7 and 8, filed 5/9/03, are acknowledged. Claims 18-35 and 37-50 are withdrawn from consideration as being drawn to non-elected Groups.

Based on a telephone interview on 2/21/03, Applicant was allowed to elect up to 10 sequences for the sequence election requirement.

Applicant's traversal is on the grounds that Groups I and VI should be combined as the claims are limited to the use of compounds having activity in the screening claims.

Applicant's request to combine Groups I and VI into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

First, Applicant presented no argument or reasoning as to why these Groups should be combined. Second, as summarized on pages 4 and 5 of the Restriction Paper, mailed 1/27/03, Groups I and VI are directed to a process and method that comprise different means and produce different results/goals. Group I identifies agents using putative modulating materials via cell contact which is different from the results of Group VI. Group VI treats and protects an entity from cancer which is a process not found in the Group I. These distinct processes and methods are often separately characterized and published in literature and would add undue search burden

if they were examined together. Thus, they are considered distinct invention types for restriction purposes.

The requirements are still deemed proper and are therefore made FINAL.

Claims herein under examination are 1-3 (amended), 4, 5 (amended), 6-8, 9 (amended), 10, 11-15 (amended), 16, 17, 51 (new), and 52 (new).

Claim Objections

Claims 2, 4-8, 10, and 51 are objected to due to the inclusion of subject matter which has been non-elected due to a restriction requirement and therefore withdrawn from consideration. The non-elected subject matter in claims 2, 4-8, 10, and 51 is summarized as follows: Claims 2, 4-8, 10, and 51 contain sequences, such as sequences other than SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032, which are non-elected subject matter. Removal of non-elected subject matter is requested. Claim 5 is also objected to due to its dependency form claim 4.

Claim 8 is objected to for the following minor informality: "squamous cell carcinoma cell" is redundant in the use of the word "cell". Correction of this redundancy is requested.

Specification

The disclosure is objected to because of the following informalities: On page 9, line 24, "1-1-92" is confusing. Appropriate correction is required.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claims 1-17, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 which correspond to nucleic acid sequences. SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 and their full complements meet the written description provisions of 35 U.S.C. 112, first paragraph. However, due to the open claim language of "containing a gene that corresponds to a polynucleotide" (claim 1) and "comprising a nucleotide sequence corresponding to a gene" (claim 52), these claims encompass sequences which do not meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by these claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032, the skilled artisan cannot envision the detailed chemical structure of the encompassed

polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 and their full length complements, but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 51, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 52 (lines 4) recites the phrase "a polynucleotide *comprising* a nucleotide sequence corresponding to a gene" which is vague and indefinite. Due to the open claim language of "comprising", it is unclear if "a polynucleotide" includes the full-length sequence of a particular sequence or just a fragment of a particular sequence. For example, a hybridization probe which is a fragment may be considered to correspond to a gene via the usage of such a probe for detection. Clarification of the metes and bounds of the instant claims is required.

Claims 1 (line 3) and 52 (line 4) recite the terms "corresponds" and "corresponding", respectively, which are vague and indefinite. It is unclear what criteria and to what extent the sequence must be similar to a gene to be considered to have the "corresponding" attribute. For example, a nucleotide sequence corresponding to a gene could be the full-length nucleotide sequence of that gene. Another interpretation is that the nucleotide sequence may include a sequence similar to the gene but with modifications made at various nucleotides and several other scenarios. Clarification of the metes and bounds of the instant claims is required. Claims 2-17 and 51 are also rejected due to their direct and indirect dependency from claim 1.

Claims 1 and 52 recite the terms "increased" (line 5 of both claims; line 11 of claim 1; and line 14 of claim 52), "elevated" (line 6 of both claims; line 12 of claim 1; and line 12 of claim 52), "increase" (line 11 of claim 1 and line 11 of claim 52), "decrease" (line 13 of claim 1 and line 13 of claim 52) which are vague and indefinite. It is unclear what threshold Applicants intend to use for determining if expression is significantly increased, elevated, or decreased as it

is well known that while scientific data may be different, it may not be significantly different if variations are caused by fluctuations including experimental processing or measurement error. Clarification of the metes and bounds of these terms is requested. Claims 2-17 and 51 are also rejected due to their direct and indirect dependency from claim 1.

Claims 1 and 52 recite the phrases "cancerous cell over that in a non-cancerous cell" (claim 1 [lines 5-6 and 14] and claim 52 [lines 5 and 14]) and "non-cancerous cell over that in a cancerous cell" (claim 1 [lines 6-7 and 12] and claim 52 [lines 6 and 12]) which is vague and indefinite. Besides their cancerous status, it is unclear in what aspects these cells are related, such as if these cells are from the same or different type of organ tissue as well as the same or different type of organism which would aid in determining test relevancy. Clarification of the metes and bounds of these phrases is requested. Claims 2-17 and 51 are also rejected due to their direct and indirect dependency from claim 1.

Claims 1 (line 7) and 52 (lines 6-7) recite the phrase "under conditions" which is vague and indefinite. It is unclear how these particular conditions are defined as they may currently be in the presence or absence of modulating compounds. Clarification of the metes and bounds of these terms is requested. Claims 2-17 and 51 are also rejected due to their dependency from claim 1.

Claim 15 recites the term "first" which is vague and indefinite. It is unclear what the "first" is in reference to as being before. Clarification of this term via clearer claim wording is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 51, and 52 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Young et al. (WO 01/94629).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Young et al. disclose a process of screening novel drugs using genes, including oncogenes (page 2, lines 12-17). Young et al. disclose using a set of genes whose expression, non-expression, or change (increase or decrease) in expression, are indicative of cancerous or non-cancerous status of a given cell (page 2, lines 22-25). Young et al. disclose sequences of SEQ ID NO: 1-8447 or sequences substantially identical to these sequences, some of which are complete or near matches to SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 of the instant invention (see Sequence match listings and following paragraph). Young et al. disclose using signature gene sets for assaying the ability of chemical agents to modulate

expression of the gene sets up or down (page 3, first paragraph). Young et al. disclose using gene sequences expressed in lung adenocarcinoma, neuroendocrine carcinoma of the lung, and lung squamous cell carcinoma (page 18, third paragraph). Young et al. disclose using chemical agents known for their ability to modulate cancerous genes (page 3, paragraphs 3 and 4). Young et al. disclose producing a product including collected data with respect to the agent used in the screening process (page 5, first paragraph). Young et al. disclose identifying genes that are expressed at higher levels in cancer cells than in normal cells or expressed at lower levels in cancer cells than in normal cells (page 6, second paragraph). Young et al. disclose exposing cells to chemical agents, determining changes in expression wherein a change is indicative of anti-neoplastic activity (page 6, third paragraph). Young et al. disclose comparing chemical agent exposure versus no exposure to the genes (page 7, first paragraph). Young et al. disclose the chemical agent modulates expression in one, two, three, five, or ten genes, or where all genes are modulated (page 7, second paragraph). Young et al. disclose the agent can be an apoptosis-inducing agent (in claim 21) inducing cell death (page 27, third paragraph). Young et al. disclose in claim 24 the gene number increases which is replication.

Due to the open claim language of "a gene that corresponds to a polynucleotide" (claim 1) and "a polynucleotide comprising a nucleotide sequence corresponding to a gene" (claim 52), a prior art polynucleotide need not be 100% identical, although most of those described below are an exact match. Young et al. disclose a sequence (ABL65541) which is 100% identical to SEQ ID NO: 851 of the instant invention. Young et al. disclose a sequence (ABL65685) which is 100% identical to SEQ ID NO: 995 of the instant invention. Young et al. disclose a sequence (ABL65308) which is 100% identical to SEQ ID NO: 1021 of the instant invention. Young et al.

disclose a sequence from (ABL64298) which is 100% identical to SEQ ID NO: 1062 of the instant invention. Young et al. disclose a sequence (ABL65990) which is 100% identical to SEQ ID NO: 1300 of the instant invention. Young et al. disclose a sequence (ABL62811) which is 100% identical to SEQ ID NO: 1340 of the instant invention. Young et al. disclose a sequence (ABL66173) which is 99.4% identical to SEQ ID NO: 1483 of the instant invention. Young et al. disclose sequences (ABL62348, ABL65156, ABL66239, ABL66834, ABL67495) which are 99.2% identical to SEQ ID NO: 1549 of the instant invention. Young et al. disclose a sequence (ABL66669) which is 97.8% identical to SEQ ID NO: 1979 of the instant invention. Young et al. disclose sequences (ABK64299 and ABL66722) which are 100% identical to SEQ ID NO: 2032 of the instant invention.

Thus, Young et al. anticipate the instant invention.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (P/N 6,232,065) in view of GenBank (various Accession numbers), Young et al. (WO 01/94629), and Kinzler et al. (P/N 5,702,903).

Robinson et al. describe methods and compositions for screening factors that affect the expression patterns of individual genes or groups of genes in various disease states such as from normal, colon cancer, and other metastatic tissue samples (col. 1, lines 4-10; col. 12, lines 17-44; and col. 23, lines 12-38). Robinson et al. describe studying the effects of exogenously added compounds (col. 22, lines 59-62) on thousands of genes including multiple genes from specific gene families (col. 13, lines 1-22) which is reasonably interpreted as a signature gene set. Robinson et al. describe comparing metastatic cancer tissue with non-metastatic cancer tissue to identify differentially expressed genes as markers of metastatic potential (col. 16, lines 19-22). The presence or absence of these markers can then be assessed in various clinical cancer isolates (col. 16, lines 22-24). Robinson et al. describe anti-cancer compounds (col. 16, line 31) and drug screening to look for compounds to alter genes known to be implicated in a disease state, such as gene over-expression or under-expression in cancer cells as opposed to normal cells (col. 16, lines 48-57). Robinson et al. provide an assaying example such that if a gene family member is known to be overexpressed in cancer cells (compared to normal cells), then one can look for drugs that reduce the expression of the suspect gene to normal levels (col. 16, lines 52-57). Robinson et al. describe variations of such comparisons are included in their invention (col. 16, lines 58-60). Robinson et al. describe examining an entire gene family expression profile and identifying important marker genes that can be used in future experiments to identify cancer and other cancer-related testing (col. 17, lines 4-19). Robinson et al. describe providing results for gene expression levels. Robinson et al. describe results being presented in a comparative format including high expression in most samples, low expression in most samples, and expression limited to only a few cell types in the panel (col. 20, lines 48-58) which exemplifies various

degrees of expression. Robinson et al. describe many of the multiple genes showing expression changes in a particular tyrosine kinase gene family set (col. 21, lines 9-27 and col. 23, lines 12-38) as mentioned in claims 47-49. Robinson et al. describe using an assortment of tissues from various organs, including from a lung carcinoma cell line (Table 1). Robinson et al. describe using adenocarcinoma cell lines, glioblastoma, and neuroblastoma cells in Table 1. Robinson et al. describe various gene modulating compounds such as drugs, growth factors, cytokines, and hormones that can affect neoplastic activity of cancerous cells upon contact (col. 22, lines 59-67). Robinson et al. describe an increased concentration of cancerous cells which is an accelerated replication compared to normal cells (col. 23, lines 28-38). Robinson et al. do not describe the use of squamous carcinoma cells, a decrease in neoplastic activity due to cell death, and particular sequences (SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032) that are elected in the instant invention.

Young et al. describe the use of squamous carcinoma cells and neuroendocrine carcinoma of the lung (page 18, third paragraph). Young et al. describe in claim 21 that the agent is an apoptosis-inducing agent. Young et al. describe a process of screening novel drugs using genes, including oncogenes (page 2, lines 12-17). Young et al. describe using a set of genes whose expression, non-expression, or change (increase or decrease) in expression, are indicative of cancerous or non-cancerous status of a given cell (page 2, lines 22-25). Due to the open claim language of "a gene that corresponds to a polynucleotide" (claim 1) and "a polynucleotide comprising a nucleotide sequence corresponding to a gene" (claim 52), a prior art polynucleotide need not be 100% identical, although most of those described below are a complete match. GenBank describes a sequence (Accession Number AA432248) which is 100% identical to SEQ

ID NO: 851 of the instant invention. Young et al. describe a sequence (ABL65541) which is 100% identical to SEQ ID NO: 851 of the instant invention. Young et al. describe a sequence (ABL65685) which is 100% identical to SEQ ID NO: 995 of the instant invention. GenBank describes a sequence (Accession Number H18957) which is 100% identical to SEQ ID NO: 995 of the instant invention. GenBank describes a sequence (Accession Number AW967462) which is 99.7% identical to SEQ ID NO: 1021 of the instant invention. Young et al. describe a sequence (ABL65308) which is 100% identical to SEQ ID NO: 1021 of the instant invention. Young et al. describe a sequence from (ABL64298) which is 100% identical to SEQ ID NO: 1062 of the instant invention. GenBank describes a sequence from liver/spleen tissue (Accession Number N71027) which is 99.8% identical to SEQ ID NO: 1062 of the instant invention. Young et al. describe a sequence (ABL65990) which is 100% identical to SEQ ID NO: 1300 of the instant invention. GenBank describes a sequence (Accession Number AA410986) which is 100% identical to SEQ ID NO: 1300 of the instant invention. GenBank describes a sequence (Accession Number AA620885) which is 100% identical to SEQ ID NO: 1340 of the instant invention. GenBank describes a sequence (Accession Number AI368878) which is 99.6% identical to SEQ ID NO: 1340 of the instant invention. Young et al. describe a sequence (ABL62811) which is 100% identical to SEQ ID NO: 1340 of the instant invention. GenBank describes a sequence (Accession Number N52026) which is 99.4% identical to SEQ ID NO: 1483 of the instant invention. Young et al. describe a sequence (ABL66173) which is 99.4% identical to SEQ ID NO: 1483 of the instant invention. GenBank describes a sequence (H98215) which is 99.2% identical to SEQ ID NO: 1549 of the instant invention. Young et al. describe sequences (ABL62348, ABL65156, ABL66239, ABL66834, ABL67495) which are 99.2%

identical to SEQ ID NO: 1549 of the instant invention. GenBank describes a sequence (Accession Number T87560) which is 97.8% identical to SEQ ID NO: 1979 of the instant invention. Young et al. describe a sequence (ABL66669) which is 97.8% identical to SEQ ID NO: 1979 of the instant invention. GenBank describes a sequence (AW275150) which is 97% identical to SEQ ID NO: 2032 of the instant invention. GenBank describes a sequence (AI521564) which is 97% identical to SEQ ID NO: 2032 of the instant invention. Young et al. describe sequences (ABK64299 and ABL66722) which are 100% identical to SEQ ID NO: 2032 of the instant invention.

Kinzler et al. describe measuring a gene product that is elevated over that which is normally produced by non-cancerous cells (col. 5, lines 51-54). Kinzler et al. describe these elevated expressions may be present in various tumors such as from lung, colorectal, and stomach (col. 5, lines 55-60). Kinzler et al. describe using non-cancerous cells for determining baseline expression levels (col. 5, lines 60-67). Kinzler et al. describe methods and kits for detecting elevated expression and identifying compounds which interfere with gene products (col. 3, lines 19-24).

Robinson et al. state their invention provides a means to generate and monitor gene expression profiles resulting from cellular and physiological changes that can then be characterized for individual genes or groups of genes (col. 1, lines 4-10). Robinson et al. state their invention may be used to screen drug compounds that affect biological samples (col. 16, lines 48-52). Robinson et al. state that human cancer is a result of genetic changes that result in alterations in the profile of expressed genes (col. 1, lines 30-33). Robinson et al. note the importance of methods that can measure the expression levels of thousands of genes to monitor

the progression of cancer (col. 1, lines 33-39). Robinson et al. state their invention may be used to compare normal and cancerous tissue as well as to differentiate between cancerous tissue that is metastatic and non-metastatic (col. 15, lines 61-67). Robinson et al. describe using tissues from various types of organs as seen in Table 1. Robinson et al. state that various modifications and variations can be made to their invention (col. 30, lines 13-18). Young et al. describe genes analyzed therein exhibit differential expression over control non-cancerous cells. A person of ordinary skill in the art would have been motivated to combine other sequences from various parts of the body to the screening process presented by Robinson et al. and to compare them with known non-cancerous controls as stated by Kinzler et al. and Young et al. to check for the presence of gene expression alterations involved in normal and cancerous tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to test compounds on the various sequences described in the paragraph above which come from various parts of the body as well as comparing genes with known differential expression between cancerous and non-cancerous cells, as one of ordinary skill in the art would have a reasonable expectation of success to identify which compounds are effective in controlling expression and where in the body this control takes place, as stated by Robinson (col. 16, lines 48-57 and col. 22, lines 1-9 and 59-62).

Thus, Robinson et al., in view of GenBank (various Accession numbers), Young et al., and, and Kinzler et al. motivate claims 1-17 and 51-52.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 10, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER